![center for scientific review logo] **peer review notes**
**may 2012**

## In This Issue

## Moving Forward After an Unsuccessful A1 Application



We know tighter NIH budgets and paylines are having real effects on researchers in the community. We have heard the anxious voices of those who have had to step back, rethink their research plans, and develop a significantly new application after an unsuccessful A1 resubmission.

Since the Center for Scientific Review (CSR) plays a key role in applying the guidelines and determining whether or not an application is a new one, we decided to share what we can to help you move forward if you face this challenge.

### Knowing How NIH Defines a New Application

Though the definition is not new, you will want to make sure you understand how NIH defines a new application:

- A new application is expected to be substantially different in content and scope, with more significant differences than are normally encountered in a resubmitted application.
- There should be fundamental changes in the questions being asked and/or the outcomes examined.
- Changes to the research plan should produce a significant change in direction and approach for the research project.

This means that, for your application to be considered new, it needs to have significant and fundamental changes in the experimental plans that produce a significant change in direction and approach.

### Assessing Whether a New Application Is New

Referral, Review and Program Officers, as well as reviewers, may find your new application is very similar to an application(s) you or your close colleagues submitted earlier. If this happens, scientists in CSR will carefully compare them. Our evaluation goes beyond simple comparisons of key words and comparisons of specific aims. CSR scientists will compare the entire research strategy of the applications in question. While there is no simple yardstick to define what makes an application new, a number of factors are considered and, in the end, it is the difference in your research plans that we most carefully examine.

## Developing a New Application After an Unsuccessful A1 Resubmission

You may find it helpful to compare your new application with your old A1 application and ask yourself:

- Are the differences in my new application consistent with a resubmission—did I write it as the A2 resubmission of an old application?
- Are many/most/all of the changes responsive to weaknesses identified in the previous critiques?
- Are most of the research questions posed in the old application also in the new one?
- Are the majority of outcomes expected in the old research plan also found in the new one?

If you answered "yes" to these questions, your new application is not likely new because you are asking the same basic questions and expecting the same set of answers in most parts of both applications. If the changes in your new application are mostly in response to the previous critiques, your application is probably not new enough.

## Responding When CSR Has Identified an Unallowable (A2) Resubmission

If there is a problem with your new application, a scientist from CSR's Division of Receipt and Referral (DRR) will notify you and your institutional representative. If you think there are still good reasons for us to consider your application new, you may send us a short rebuttal letter. Before you do, you should discuss this with a DRR scientist. Your letter and all relevant applications will be provided to a second group of CSR/NIH scientists. They will re-evaluate the similarity of the applications using the new information you provide. The most helpful letters we receive include the following:

- A brief aim by aim comparison of the research plans.
- Clarification of how any apparently minor changes in research strategy will lead to significantly different data in the new application.
- A description of how your new research plans will take the work in a significantly new direction.

After reviewing the feedback from this group of scientists, DRR will let you know if it considers your application a new one.

## Moving Forward After an Unsuccessful A1 Resubmission

You still have options for moving your science forward in a future application even if your current application is not accepted for review:

- Consider deconstructing your research plans. Ask yourself: "what other important questions need to be asked in my research area?" Then take the work in a new direction and submit a new application.
- Apply for a different kind of grant when you have your summary statement in hand. Some of the stronger research aims you originally proposed in an R01 application, for instance, may be proposed in an R21 application so long as you follow the requirements for this smaller and different type of grant. There is no limit to the amount of overlap if you apply for a different type of grant.
- Consider putting the aims and approach in your unsuccessful A1 application on hold until 37 months after your A0 (not A1) submission. After this time, the same application will automatically be considered new. Of course, you'll want to update your application based on changes in the field during that time.

***Hint: You can get the equivalent of three reviews if before you submit a new application you share it with experienced applicants. (Just don't ask a reviewer on the panel that would likely review your application.) You will get the benefit of their critiques but still have two chances to get NIH funding.***

NIH surveyed members of the scientific community last year to collect their thoughts on NIH's resubmission policy and other policy changes. A report is expected in November 2012. If you wish to share your thoughts on this or any other NIH policy, visit the NIH Feedback website.

**Getting More Information**

- NIH Policy on Resubmission Applications
- CSR's Evaluation of Unallowable Resubmission and Overlapping Applications

# CSR to Use eRA Commons to Communicate with Applicants and Their Organizations

CSR's Division of Receipt and Referral will soon communicate with applicants and their organizations via eRA Commons. You will be notified by email to check your Commons account when 1) additional information is required before your application can be assigned to a scientific review group and NIH Institute or Center for funding consideration; 2) your request for an IC assignment cannot be honored; or 3) your application does not comply with NIH policy. To avoid delays, it is vital that all Grantee Organizations, Principal Investigators and Individual Fellows are registered in the eRA Commons and all email addresses are checked periodically for accuracy.

# Peer Review Notes Goes All Digital

To keep in step with the times, we've converted the Peer Review Notes newsletter into an all-digital publication. Your Scientific Review Officer will either send you an email with a link to the latest issue or upload the link to the meeting materials section in the Internet Assisted Review system.

**If you want to make sure you see the newsletter when it is released,** join the CSR Peer Review Notes Listserv.

# Is it Human Subjects Research or Not?



Reviewers and applicants sometimes ask for help figuring out whether or not an application is proposing human subjects research. Since getting this right is so important to submitting a viable application and conducting a good review, we thought it would be helpful to note the most important things you should know.

**The definition is simple:** Research in which an investigator obtains either data through intervention or interaction with a living individual OR identifiable, private information is considered to be human subjects research. The exemptions and qualifiers, however, take some time to understand.

**Exempted human subjects research:** There are six categories of human subjects research that meet the above definition but involve such low risk that they are exempt from human subjects regulations. If an application qualifies for one of them, the Human Subjects Section must provide a justification for the exemption that enables reviewers and NIH staff to determine whether it is appropriate. It is not necessary for this section in an exempted application to address the risks, protections, benefits and importance of the knowledge to be gained. This information is only required for nonexempt human subjects research applications.

Most NIH-funded research involving human subjects is not exempt. NIH does, however, receive some applications that qualify for exemptions. The following exemptions are the most common for NIH grants:

**E1: Research conducted in educational settings on educational practices** such as instructional strategies, techniques, curricula and class room management methods.

**E2: Research involving the use of educational tests, surveys, interviews or observation of public behavior unless** information is recorded in a way that permits the identification of subjects, and disclosure outside the research could cause them harm. This exemption does not apply to most research with children.

**E4: Research involving the study of existing data, documents, records, specimens if publicly available OR if recorded by the investigator in a manner that subjects cannot be identified directly or indirectly may qualify for the E4 exception.** To qualify for E4:

- The investigator initially obtains identifiable data or specimens AND
- The investigator records the information in such a manner that subjects cannot be identified AND
- The data or specimens must all be existing when the research begins.

*Examples*

- An investigator accesses medical records or a dataset from a prior study that has identifiers and pulls off only select data into a research data set that does not have identifiers. Once this data set has been created, it cannot be linked back to the original data set or to identifiers.
- An investigator goes to a stored set of serum samples labeled with identifiers. She selects the samples of interest but then removes the labels and retains only basic clinical information about the subjects. The samples she will use in her research can no longer be linked to identifiers.

An E4 application is the only exempted application that does not need to include information on the inclusion of women, minorities and children. It is also important to note there are no exemptions for human subjects research involving prisoners.

### When Is Research Involving Human Data or Specimens Not Human Subjects Research?

Research that involves the use of existing samples or data not collected for the proposed research can be difficult to categorize. However, the key factor in determining if human subjects are involved is whether the investigators have access to identifiers for the subjects to whom the data or specimens pertain:

- If none of the investigators involved in the proposed research has the ability to identify the subjects who provided the samples/data, it is not considered to be human subjects research.
- If any of the investigators maintains the ability to identify subjects, it is non-exempt human subjects research.

Keep in mind that anyone involved in any aspect of the research, other than simply providing samples or data, is considered to be an investigator in the research.

### Beta Testing and Collection of Expert Advice Is Not Human Subjects Research

Research involving the collection of expert advice and Beta Testing is usually not considered human subjects research.

*Examples*

- Research using expert consultants to improve research design or provide advice on the research process.
- Research where individuals test a new product to identify flaws.
- Pilot tests of new products, though such research may be considered human subjects research if it involves collecting identifiable private information.

**Get More Information**

- [FAQs on Human Subjects Research - Human Specimens, Cell Lines or Data](#)
- [Private Information or Biological Specimens Decision Chart](#)

## Hybrid Video and Face-to-Face Reviews: The Best of Both Worlds?



We recently gave reviewers in a couple of study sections a choice: They could come to a face-to-face review meeting in Bethesda or connect to the same meeting via a secure video link from their home or office. The meetings were hosted at CSR in meeting rooms with four large monitors on the walls.

One of the meetings was a special emphasis panel organized by [Dr. Malgorzata Klosek](#). To see how things went, we interviewed the chair: Dr. Warren Johnson, who is the Director of the Center for Global Health at Weill Cornell Medical College.

He had some trepidation about video reviewers before the meeting, and he wondered, "Would they be diligent or disappear if they weren't interested in an application? And how could they responsibly score the application?"

"I was pleasantly surprised. The video reviewers were active participants through the whole meeting," he said. "Frankly, I got used to it. They were at the end of the room. I could look up and see them. It was almost as if they were at the end of a long table."

We also asked one of the video reviewers what he thought. "The meeting went very well," said Dr. Oladele Ogunseitan, who linked in to the meeting from The University of California in Irvine. "It was just like being there," he said. "The video connection was excellent, and I was able to read 'body language.'" He then explained, "I had to connect very early in the morning, but this was way more convenient than traveling across the country."

"Hybrid meetings allow peer review to be more user friendly," said [Dr. Eileen Bradley](#), Chief of CSR's Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group. "Sometimes reviewers simply can't travel . . . they have responsibilities for their labs, coworkers, friends and family. Life happens. People get sick, sons and daughters graduate and get married. And even if something happens at the last minute, we can usually bring them in by video."

Dr. Bradley started piloting hybrid video meetings in 2003 because she found it so hard to recruit physicians, small business and other reviewers to serve on her review groups. But these meetings were hampered by the limitations of the video technology available. "One slow connection used to slow the whole meeting," she said. "But CSR recently acquired new video conferencing technology and services that makes video enhanced review meetings more reliable and useful."

The majority of reviewers participating in the meeting Dr. Johnson chaired traveled to Bethesda. The proportion of reviewers choosing to connect via video varies from meeting to meeting. "I think you need a critical mass to be in the room," said Dr. Johnson. "Though I don't know what that is." In assessing the effectiveness of hybrid meetings, CSR will look at the ratio of face-to-face and video reviewers and continue to ask reviewers for input.

This year, we have piloted five meetings and we expect to pilot about seven more this spring as we continue to test the technology and develop best practices. Though all of these meetings were held in CSR conference rooms, we plan to pilot a hybrid video meeting at a local hotel this spring.

"CSR is proceeding carefully," said Dr. George Chacko, Director of CSR's Office of Planning, Evaluation and Analysis. "We want any decision to expand the use of hybrid meetings to be supported by an evaluation of meeting data and an understanding of key stakeholder preferences."

Still, there is no doubt there is a lot of enthusiasm for hybrid reviews. "Our reviewers love it," said Dr. Bradley. "Program Officers also like it because they can easily access the meeting from their desktop."

Dr. Ogunseitan shares this enthusiasm. "The video format is clearly my preferred form of participation in review panels hosted on the East Coast," he said, "especially where a lot of the reviewing is already done online. The technology worked well, and it will even get better, so I strongly encourage NIH to invest in this."

## CSR's Early Career Reviewer Training Program Is a Hit



"The feedback from our Early Career Reviewers (ECRs) has been impressive," said CSR Acting Director Dr. Richard Nakamura. "They are learning a lot, and we're thrilled to be enhancing and diversifying our pool of reviewers for the future."

"The experience gave me important insight into how the review process really works and what it takes to be an effective reviewer," said Dr. Cheryl Dickter, assistant professor of psychology at The College of William & Mary. "I also made great connections with some of the other reviewers on the panel."

Dr. Nakamura noted that providing such useful experiences to emerging scientists is one of the main goals of the ECR program. "A high priority is also given to engaging ECRs from less research intensive institutions and scientists who will increase the diversity of our review groups," he said. "The highest priority, however, is to engage ECRs with the most appropriate expertise needed by the specific review group. As a result, any qualified researcher is encouraged to apply."

One of the most enthusiastic ECRs may be Dr. Raphael Isokpehi, who is an associate professor of biology and the Director of the Center for Bioinformatics in Computational Biology at Jackson State University in Mississippi. "When I write proposals now, I am able to be more critical and better calibrate the overall impact," he said.

He also said the payoff was tangible: "After my participation . . . I submitted proposals for a Research Education Grant (R25) and a Specialized Collaborative Center Cooperative Agreement (U54). Both were scored with the U54 receiving a great score!"

Dr. Isokpehi said his U54 application benefitted directly from his ECR experience because his proposed research included a collaboration developed with a reviewer he met on his study section. He said he also met a renowned researcher in metagenomics on his study section, "I was able to gain more knowledge on bioinformatics tools and methods, which I've used to expand my research."

"It's a win-win situation," said Dr. Nakamura. "So we're looking for more volunteers, and we encourage all of our Scientific Review Officers [SROs] to recruit ECRs for their meetings if they have the needed expertise."

**What is expected?** ECRs will participate in a CSR study section meeting once a year for up to two years, serving as the third reviewer on two to four NIH grant applications each time. This lighter review load will help ECRs stay focused on advancing their research careers. Our SROs and study section chairs mentor ECRs like they do new study section members to ensure their reviews are helpful.

**What are the requirements?** We are looking for researchers who have a faculty position or equivalent; who have an active, independent research program; who are published in peer reviewed research journals; and who have not reviewed for CSR in a face-to-face meeting. An ECR does not necessarily need to have NIH or equivalent funding.

**How do you apply?** Send your current CV along with a list of terms that describe your scientific expertise to us at CSREarlyCareerReviewer@mail.nih.gov.

## What's Hot on CSR's Website

CSR recently overhauled its Website, and we wanted to tell you where the hot links are and encourage you to share them with your webmasters so researchers at your institution have access to our best information.

CSR's Homepage

NIH Peer Review Videos

Planning, Writing, and Submitting Your Application

What Happens to Your NIH Grant Application

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